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To: "'wvogl@samhsa.gov'" <wvogl@samhsa.gov>
Date: Thu, Oct 11, 2001 9:53 AM
Subject: Comments on Federal Register Notice: August 21, 2001 (Volume 66,Number 162)

Walt,

I just realized that comments on this document were to be sent to Parklawn by October 12th. As I'm afraid I missed that deadline, I'll just submit my 2 comments to you via Email. If you still need them submitted in writing, let me know and I'll copy my Email and send it through the mail.

I found the document clear and concise. You all did a great job. My only comments are:

1. It seems like there might be a contradiction concerning the urine being used for "any other testing," versus just "other drug testing." You might want to check the following 2 sections:

Background section, Subpart B- Scientific and Technical Requirements, 2nd paragraph, states that "The Secretary proposes to revise paragraph 2.1(c) to clarify that other DRUG tests are not normally permitted on urine specimens.

Whereas, further in the document in Subpart B, it states that "section 2.1, revise paragraph (c) to read as follows: (c) Urine specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines shall not be used for ANY OTHER ANALYSIS or test unless authorized by an agency's drug-free workplace program.

2. I'd also like to make an additional comment regarding FDA and tests to detect adulterants. This comment is not specifically related to the contents of this Notice, but is only a general point of clarification for you...
I think SAMHSA is already aware that FDA determined that tests intended for detection of adulterants are not medical devices, and as such, will not review them or give them FDA clearance. However, if a manufacturer submits a test which has dual claims, medical and for detecting adulterants, we would review it. We would simply review it in the context of medical use, and not in the terms of how effective it is to detect adulterants.

Thanks for the opportunity to comment.

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